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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,907	03/09/2004	Duran Yetkinler	SKEL-012CIP	3390

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/797,907		YETKINLER ET AL.	
	Examiner		Art Unit	
	Anu Ramana		3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-45 and 47-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-45 and 47-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/5/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 40 is objected to because of the following informalities. In line 2, insert - - cement - - before "is vibrated" to correct a minor typographical error. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by T epic (US 4,463,875).

T epic discloses a system or "kit" with a cement composition introduction element (28, 84), a vibratory element with a holder 78 and an implantable hardware device C (Figs. 1, 5 and 7, col. 6, lines 4-68, col. 7, lines 1-63 and col. 10, lines 49-68).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-42, 44-45, 47-50 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US 6,610,079) in view of T epic (US 4,463,875) and Ison et al. (US 5,496,399).

Li et al. disclose a system or "kit" including a cement introduction element and a fixation or "implantable hardware" device such as a screw and a method for implanting a

fixation device, such as screw, by delivering cement to the screw wherein the screw is used to attach a plate to a fractured bone (Fig. 9 and col. 11, lines 4-49).

Li et al. disclose all elements of the claimed invention except for: (1) a calcium phosphate cement; and (2) vibration of the cement as it is being delivered to the target bone site.

Tepic teaches a vibratory element attached via a holder 78 to a handle 28 of a cement delivery device wherein vibrations are imparted at 60 Hz to cause cement to penetrate relatively deeply into the cavity in which the cement is being placed (Fig. 5, col. 1, lines 5-10, col. 2, lines 48-62, col. 4, lines 53-64, col. 7, lines 61-63 and col. 10, lines 49-68).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached a vibratory element as taught by Tepic to the Li et al. cement delivery device to enhance cement penetration.

The use of calcium phosphate cements due to their superior biocompatibility compared to polymeric cements is very well known in the art, as demonstrated by Ison et al. (col. 1, lines 17-67 and col. 2, lines 1-2). Accordingly, it would have been obvious to one of ordinary skill in the art to have used a calcium phosphate cement in the method of the combination of Li et al. and Tepic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein biocompatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 39, the combination of Li et al., Tepic and Ison et al. discloses all elements of the claimed invention except for the claimed range of vibration frequencies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized vibration frequencies in a range of 0.1 to 100,000 Hz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 33-45 and 47-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karpman et al. (US 6,214,012) in view of Tepic (US 4,463,875) and Ison et al. (US 5,496,399).

Karpman et al. disclose the method steps of: positioning a hardware device such as a cannulated screw 30 in conjunction with any number of conventional fixation devices such as wires, plates, rods at a target bone site including cancellous bone; and delivering cement to the target bone site by a cement gun for internal fixation following fracture reduction (Figs. 3 and 4, col. 5, lines 5-67, col. 7, lines 5-29 and col. 9, lines 24-54).

Karpman et al. disclose all elements of the claimed invention except for: (1) a calcium phosphate cement; and (2) vibration of the cement as it is being delivered to the target bone site.

Tepic teaches a vibratory element attached via a holder 78 to a handle 28 of a cement delivery device wherein vibrations are imparted at 60 Hz to cause cement to penetrate relatively deeply into the cavity in which the cement is being placed (Fig. 5, col. 1, lines 5-10, col. 2, lines 48-62, col. 4, lines 53-64, col. 7, lines 61-63 and col. 10, lines 49-68).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached a vibratory element as taught by Tepic to the Karpman et al. cement delivery device to enhance cement penetration.

The use of calcium phosphate cements due to their superior biocompatibility compared to polymeric cements is very well known in the art, as demonstrated by Ison et al. (col. 1, lines 17-67 and col. 2, lines 1-2). Accordingly, it would have been obvious to one of ordinary skill in the art to have used a calcium phosphate cement in the method of the combination of Karpman et al. and Tepic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein biocompatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claim 39, the combination of Karpman et al., Tepic and Ison et al. discloses all elements of the claimed invention except for the claimed range of vibration

frequencies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized vibration frequencies in a range of 0.1 to 100,000 Hz, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on June 1, 2006 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
August 17, 2006

Anuradha Ramana


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER